REMARKS

Applicant through his attorney expresses appreciation for the opportunity to discuss with the Examiner by telephone, on August 9, 2002, certain aspects of the claims, restriction requirement, and election of species for the purpose of closing the restriction and electing a species as the basis for the Examiner to examine the claims.

In the Office Action, Claims 17-35 were restricted as follows:

Group I: Claims 31-35 as "embracing **prophylactic** methods of using a plasmid-based vaccine of increasing the level of HDL, reducing the level of endogenous CETP, increasing antibodies to CETP, or treating any cardiovascular disease in a human or other animal in need of treatment thereof"

Group II: Claims 31-35 as "embracing **therapeutic** methods of using a plasmid-based vaccine of treating any cardiovascular disease in a human or other animal treatment thereof"

Applicant respectfully traverses the restriction requirement. As the result of the above-mentioned telephone conversation with the Examiner, and in order to close the division of the claims, Applicant has amended Claim 31 to remove the phrase "therapeutically or prophylactically" as superfluous to the recitation of an underlying, essential, special technical feature, i.e., administering a DNA plasmid-based vaccine comprising a DNA segment comprising a nucleotide sequence coding for an immunogenic polypeptide, which nucleotide sequence includes at least one segment coding for a B cell epitope of CETP linked in-frame with at least one segment coding for a broad range helper T cell epitope, which nucleotide sequence is operably linked to a promoter sequence suitable for directing the transcription of the nucleotide sequence in a mammalian cell. This is an essential technical feature found in all of pending Claims 17-35. Accordingly, all of the pending claims of this application are united by an expressed contribution over the prior art in accordance with PCT Rule 13.2, which states:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

According to the invention, administration of the specifically recited DNA plasmid-based vaccine to an individual elicits an immune response, the beneficial effects of which can be measured in various

ways, including: production of an anti-atherogenic lipoprotein profile, inhibition or clearing of the vaccinated individual's own (endogenous) CETP activity in the blood stream, production of antibodies that react with the individual's circulating CETP, and inhibition of development and progression of atherosclerotic lesions (see, e.g., Example III, especially, p. 27, lines 10-13 of the specification). Thus, every method of the pending claims of this application clearly comprises the essential step of administering a DNA-plasmid based vaccine of the invention to an individual to elicit an immune response that provides *in situ* auto-regulation of CETP activity and the cardiovascular benefits that follow from such regulation. Accordingly, all of the pending Claims 17-35, as amended herein, share a special technical feature that enables the claims to be examined as a single group in this application in accordance with PCT Rules 13.1 and 13.2.

As all claims recite the feature of administering a specifically defined DNA-plasmid vaccine, any art relevant to examination of one group of claims will necessarily be the same art that is relevant to examination of the other group of claims. Therefore there is no conservation of resources or avoidance of unnecessary search; rather, there is only needless subdivision of Applicant's unified invention by imposing the restriction requirement set forth in Paper No. 4.

In Paper No. 4, Applicant has also been required to elect a single species of DNA segment for examination. The Examiner states that each of the species does not share a common special technical feature; however, as recited directly in the claims, all of the species of DNA segments are comprised of coding sequences for a CETP B cell epitope peptide and for a broad range helper T cell epitope peptide, linked in-frame. Thus, all recited DNA segments encode an immunogenic fusion protein capable, on expression *in vivo*, of eliciting production of anti-endogenous CETP antibodies in the vaccinated individual. This shared feature should dissolve the requirement for election of a single species.

In order to be fully responsive, Applicant has elected as the basis of the examination of Claims 17-35, the species of DNA segment comprising a DNA sequence of SEQ ID NO:5. All claims encompass this species.

In view of the above comments, Applicant respectfully requests that the Examiner enter the amendment, remove the restriction and election requirements, and examine Claims 17-35 on the merits. Prompt examination and allowance of all claims is respectfully solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING

The undersigned hereby certifies that the items of correspondence referred to above are being deposited with the U.S. Postal Service as First Class mail under 37 C.F.R. §1.8, postage prepaid, in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231 on the date indicated below:

August 16, 2002
date of mailing and signature

Melanie A. McFadden
Melanie A. McFadden

Marked up version of amended Claim 35 pursuant to 37 C.F.R. § 1.121(c)(1)(ii)

31. (amended) A method for [therapeutically or prophylactically] treating cardiovascular disease in a human or other animal in need of treatment thereof comprising administering to said human or other animal a DNA plasmid-based vaccine comprising a DNA segment comprising a [the] nucleotide sequence coding for an immunogenic polypeptide, which nucleotide sequence includes at least one segment coding for a B cell epitope of CETP linked in-frame with at least one segment coding for a broad range helper T cell epitope, which nucleotide sequence is operably linked to a promoter sequence suitable for directing the transcription of the nucleotide sequence in a mammalian cell.